

**Third Parties Recognized to Review Selected Premarket
Notifications During FDA's Two-year Pilot Program**

Updated: September 17, 1996

Recognized Third Party:

British Standards Institution (BSI) Product Services
P.O. Box 375
Milton Keynes
Bucks. MK146LL
UNITED KINGDOM

or if unable to deliver to a P.O. Box:

BSI Product Services
Breckland
Linford Wood West
Milton Keynes
Bucks.
UNITED KINGDOM

Contact Person:

Dr. Peter J.C. Walker

Phone: +44-1908-324143

Fax: +44-1908-228016

Internet Address: Not available

Name and title of the most responsible individual at Third Party:

Mr. Robin A.C. Dandy, Deputy Director, Product Services

Devices authorized for review by the Third Party:

Class I Devices

Anesthesiology Panel (868)

- Breathing Mouthpiece (868.5620)
- Non-powered Oxygen Tent (868.5700)

Class I Devices (cont)

Clinical Toxicology Panel (862)

- Follicle-Stimulating Hormone Test System (862.1300)
- Gastrin Test System (862.1325)
- Glucagon Test System (862.1335)
- Immunoreactive Insulin Test System (862.1405)
- Luteinizing Hormone Test System (862.1485)
- Prolactin (lactogen) Test System (862.1625)
- High Pressure Liquid Chromatography System for Clinical Use (862.2260)
- Thin-layer Chromatography System for Clinical Use (862.2270)
- Atomic Absorption Spectrophotometer for Clinical Use (862.2850)
- Mass Spectrometer for Clinical Use (862.2860)

Dental Panel (872)

- Dental Mercury (USP) (872.3700)
- Dental Handpiece and Accessories (EBW, EFB, EFA, EGS, EKX, and EKY) (872.4200)

Ear, Nose and Throat Panel (874)

- Hearing Aid (874.3300)
- Powered Nasal Irrigator (874.5550)

Gastroenterology-Urology Panel (876)

- Urological Clamps for Males (876.5160)
- Urine Collector and Accessories (876.5250)

General Hospital Panel (880)

- Pressure Infuser for I.V. Bag (880.5420)
- Patient Examination Glove (LZB, FMC, LYY, LZA, LZC AND LYZ) (880.6250)
- Patient Lubricant (880.6375)

General and Plastic Surgery Panel - (878) All Eligible Devices EXCEPT

- Introduction/Drainage Catheter and Accessories, product codes (GBZ, GBQ, GBY, GBX, GBO, GBW, and GCB) (878.4200)

Class I Devices (cont 2)

Hematology Panel (864)

- Cultured Animal and Human Cells (864.2280)
- Automated Blood Cell Diluting Apparatus (864.5240)

Microbiology Panel (866)

- Automated Zone Reader (866.2850)
- Microbiological Specimen Collection and Transport Device (866.2900)
- Corynebacterium Spp. Serological Reagents (866.3140)
- Cocksackie virus Serological Reagents (866.3145)
- Mycobacterium Tuberculosis Immunofluorescent Reagents (866.3370)
- Mumps Virus Serological Reagents (866.3380)
- Poliovirus Serological Reagents (866.3405)
- Prealbumin Immunological Test System (866.5060)
- Human Allotypic Marker Immunological Test System (866.5065)
- Beta-Globulin Immunological Test System (866.5160)
- Alpha-Globulin Immunological Test System (866.5400)
- Alpha-1-Glycoproteins Immunological Test System (866.5420)
- Alpha-2-Glycoproteins Immunological Test System (866.5425)
- Beta-2-Glycoprotein I Immunological Test System (866.5430)
- Beta-2-Glycoprotein III Immunological Test System (866.5440)

Neurology Panel (882) - All Eligible Devices **EXCEPT**

- Ataxiagraph (882.1030)
- Skull Punch (882.4750)

Obstetrics / Gynecology Panel (884)

- Unscented Menstrual Pad (884.5435)

Ophthalmology Panel (866) - All Eligible Devices **EXCEPT**

- Intraocular Lens Guide (886.4300)

Orthopedic Panel (888)

- AC powered Goniometer (888.1500)

Class I Devices (cont 3)

Physical Medicine Panel (890)

- Hot or Cold Disposable Pack (890.5710)

Radiology Panel (892)

- Scintillation Gamma Camera (892.1100)
- Nuclear Whole Body Scanner (892.1330)
- Radiographic-Film Illuminator (892-1890)

Class II Devices

Cardiovascular Panel (870) - All Eligible Devices **EXCEPT**

- Blood Pressure Cuff (manual/non-electric devices only) (870.1120)
- Noninvasive Blood Pressure Measurement System (manual/non-electric devices only) (870.1130)

Dental Panel (872) - All Eligible Devices

General Hospital Panel (880) - All Eligible Devices

Neurology Panel (882) - All Eligible Devices

Obstetrics / Gynecology Panel (884) - All Eligible Devices

Ophthalmology Panel (886) - All Eligible Devices

Orthopedic Panel - All Eligible Devices **EXCEPT**

- Intramedullary Fixation Rod (888.3020)

Radiology Panel (892) - All Eligible Devices

Recognized Third Party:
California Department of Health Services
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234-7320

Contact Person:

James M. Barquest, Ph.D.

Phone: (916) 324-4000

Fax: (916) 322-6326

Internet Address: Not available

Name and title of most responsible individual at Third Party:

Stuart E. Richardson, Jr., M.P.H., Chief, Food & Drug Branch

**THIRD PARTY REQUESTS THAT ONLY CALIFORNIA FIRMS
SUBMIT APPLICATIONS FOR REVIEW**

Devices authorized for review by the Third Party:

Class I Devices

Clinical Chemistry Panel (862) - All Eligible Devices

Clinical Toxicology Panel (862) - All Eligible Devices

Gastroenterology-Urology Panel (876) - All Eligible Devices

General Hospital Panel (880) - All Eligible Devices

Hematology Panel (864) - All Eligible Devices

Immunology Panel (866) - All Eligible Devices

Microbiology Panel (866) - All Eligible Devices

Class II Devices

Clinical Chemistry Panel (862) - All Eligible Devices

Class II Devices (cont)

General Hospital Panel (880) - All Eligible Devices

Hematology Panel (864) - All Eligible Devices

Immunology Panel (866) - All Eligible Devices

Recognized Third Party:

CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Contact Person:

Robert Mosenkis

Phone: (610) 825-6700 ext. 141

Fax: (610) 834-1275

Internet Address: Not available

Name and title of the most responsible individual at Third Party:

Robert Mosenkis, President

Devices authorized for review by the Third Party:

Class I Devices

Anesthesiology Panel (868) - All Eligible Devices

Dental Panel (872)

- Dental Handpieces and Accessories (872.4200)

Ear, Nose and Throat Panel (874)

- Short increment sensitivity index (SISI) adapter (874.1070)
- Gustometer (874.1500)
- Air or water caloric stimulator (874.1800)
- Toynbee diagnostic tube (874.1925)
- Hearing Aid (874.3300)
- Epistaxis Balloon (874.4100)
- Powered Nasal Irrigator (874.5550)
- Antistammering device (874.5840)

Gastroenterology-Urology Panel (876) - All Eligible Devices

General Hospital Panel (880) - All Eligible Devices

Class I Devices (cont.)

General and Plastic Surgery Panel (878)

- Introduction/drainage Catheter and Accessories (878.4200)
- Removable Skin Clip (878.4320)
- Surgeon's Gloves (878.4460)
- Nonpowered, Single-patient, Portable Suction Apparatus (878.4680)
- Removable Skin Staple (878.4760)
- AC-powered, Battery-powered, and Pneumatically Powered Surgical Instrument Motor (878.4820)
- Air- or AC-powered Operating Table and Air- or AC-powered Operating Chair and Accessories (878.4960)
- Liquid Bandage (880.5090)

Neurology Panel (882) - All Eligible Devices **EXCEPT**

- Shunt System Implantation Instrument (882.4545)

Obstetrics and Gynecology Panel (884)

- Unscented menstrual pad (884.5435)

Ophthalmology Panel (886)

- Retinoscope (886.1780)
- Tonometer Sterilizer (886.1940)
- Powered Corneal Burr (886.4070)
- Intraocular Lens Guide (884.4300)
- Keratome (886.4370)
- Sunglasses (non-prescription) (886.5850)

Orthopedic Panel (888)

- AC-Powered Goniometer (888.1500)
- Calipers for Clinical Use (888.4150)

Physical Medicine Panel (890) - All Eligible Devices

Radiology Panel (892) - All Eligible Devices

Class II Devices

Cardiovascular Panel (870) - All Eligible Devices

Class II Devices (cont.)

General Hospital Panel (880) - All Eligible Devices

Neurology Panel (882) - All Eligible Devices

Obstetrics / Gynecology Panel (884) - All Eligible Devices

Ophthalmology Panel (886) - All Eligible Devices

Orthopedic Panel (888) - All Eligible Devices

Recognized Third Party:

MET Laboratories
914 West Patapsco Avenue
Baltimore, MD 21230-3432

Contact Person:

Leonard Frier, P.E.

Phone: (410) 354-3300

Fax: (410) 354-3313

Internet Address: <http://www.metlabs.com>

Name and title of the most responsible individual at Third Party:

Leonard Frier, P.E., President

Devices authorized for review by the Third Party:

Class I Devices

All Eligible Devices

Class II Devices

All Eligible Devices **EXCEPT** those in the Radiology Panel (892).

Recognized Third Party:

RDD Consultants, Inc.
401 Spruce Street
Louisville, CO 80027

Contact Person:

Nancy Sauer

Phone: (303) 665-9423

(800) IVD-510K (483-5105)

Fax: (303) 665-9413

Internet Address: NKSAUER@DASH.COM

World-Wide-Web: <http://www.dash.com/rdd510K> (available 8-5-96)

Name and title of most responsible individual at Third Party:

Nancy Sauer, President

Devices authorized for review by the Third Party:**Class I Devices****Clinical Chemistry Panel (862)**

- Andostrenedione Test System (862.1075)
- Androsterone Test System (862.1080)
- C-Peptides of Proinsulin Test System (862.1135)
- Catecholamines (total) Test System (862.1165)
- Compound S (11-Deoxycortisol) Test System (862.1185)
- Corticoids Test System (862.1195)
- Corticosterone Test System (862.1200)
- Dehydroepiandrosterone (free and sulfate) Test System (862.1245)
- Desoxycorticosterone Test System (862.1250)
- Estradiol Test System (862.1260)
- Estriol Test System (862.1265)
- Estrogens (total, in pregnancy) Test System (862.1270)
- Estrogens (total, nonpregnancy) Test System (862.1275)
- Estrone Test System (862.1280)
- Etiocholanolone Test System (862.1285)
- Follicle Stimulating Hormone Test System (862.1300)
- Gastrin Test System (862.1325)

Class I Devices (cont.)

- Globulin Test System (CGH: Electrophoretic, globulin only) (862.1330)
- Glucagon Test System (862.1335)
- Gamma-glutamyl Transpeptidase and Isoenzymes Test System (JPZ: colorimetric method, gamma-glutamyl transpeptidase and JQA: electrophoretic, gamma-glutamyl transpeptidase isoenzymes only) (862.1360)
- Human Growth Hormone Test System (862.1370)
- Histidine Test System (JMI: chromatographic, histidine only) (862.1375)
- 7-Hydroxycorticosteroids (17-ketogenic steroids) Test System (JHE: radioassay, 17-Hydroxycorticosteroids only) (862.1385)
- 17-Hydroxyprogesterone Test System (862.1395)
- Hydroxyproline Test System (862.1400)
- Immunoreactive Insulin Test System (862.1405)
- Lipoprotein Test System (JHO: electrophoretic separation, lipoproteins and JHP: radial immunodiffusion, lipoproteins only) (862.1475)
- Luteinizing Hormone Test System (862.1485)
- 5'-Nucleotidase Test System (862.1520)
- Osmolality Test System (862.1540)
- Urinary pH (Nonquantitative) Test System (862.1550)
- Pregnanediol Test System (862.1605)
- Pregnanetriol Test System (862.1610)
- Pregnenolone Test System (862.1615)
- Progesterone Test System (862.1620)
- Prolactin (Lactogen) Test System (862.1625)
- Protein (Fractionation) Test System (862.1630)
- Quality Control Material (JJX: Single (specified) analyte controls (assayed and unassayed; MKA: kit, direct antigen, negative control; MJZ: kit, direct antigen, positive control; MJY: kit, serological, negative control; MJX: kit, serological positive control) (862.1660)
- Testosterone Test System (862.1680)

Clinical Toxicology Panel (862)

- Clinical Toxicology Control Material (862.3280)

Class I Devices (cont. 2)

Hematology Panel (864)

- Adenosine Triphosphate Release Assay (862.7040)

Immunology Panel (866) - All eligible devices

Microbiology Panel (866) - All eligible devices EXCEPT

- Quality Control Material (Assayed and Unassayed) (862.1660)
- Transport Culture Medium (866.2390)
- Microorganism Differentiation and Identification Device (866.2660)
- Automated Zone Reader (866.2850)
- Microbiological Specimen Collection and Transport Device (866.2900)
- Listeria SPP. Serological Reagents (866.3355)

Class II Devices

Clinical Chemistry Panel (862)

- Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy (non-OTC use only) (862.1155(a))

Immunology Panel (866)

- C-reactive protein immunological test system (866.5270)
- Rheumatoid factor immunological test system (866.5775)

Recognized Third Party:

TUV Product Services
1775 Old Highway 8
New Brighton, MN 55112-1891

Contact Person:

Matthias H. Popp

Phone: (612) 631-2487

Fax: (612) 631-0285

Internet Address: <http://www.TUVPS.com>

Name and title of the most responsible individual at Third Party:

Matthias H. Popp, Chief Executive Officer

Devices authorized for review by the Third Party:

Will review all eligible Class I & Class II devices.

Recognized Third Party:

Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

Contact Person:

Steve Hewson, Managing Engineer, Northbrook Department 413

Phone: (847) 272-8800 ext. 43316

Fax: (847) 272-9718

Internet Address: hewsons@UL.com

Name and title of most responsible individual at Third Party:

James R. Beyreis, Vice President-Engineering

Devices authorized for review by the Third Party:

Class I Devices

All Eligible Devices **EXCEPT**

Clinical Chemistry Panel (862)

- Estrogens (Total, In Pregnancy) Test System (862.1270)
- Estrogens (Total, Non-pregnancy) Test System (862.1275)
- Estrone Test System (862.1280)
- Etiocholanolone Test System (862.1285)
- Follicle-Stimulating Hormone Test System (862.1300)

Immunology Panel (866)

- Prealbumin Immunological Test System (866.5060)
- Human Allotypic Marker Immunological Test System (866.5065)
- Beta-Globulin Immunological Test System (866.5160)
- Carbonic Anhydrase B and C Immunological Test System (866.5200)
- Factor XIII A, S, Immunological Test System (866.5330)
- Alpha-Globulin Immunological Test System (866.5400)
- Alpha-1-Glycoproteins Immunological Test System (866.5420)
- Alpha-2-Glycoproteins Immunological Test System (866.5425)
- Beta-2-Glycoprotein I Immunological Test System (866.5430)
- Beta-2-Glycoprotein III Immunological Test System (866.5440)

Class I Devices (cont.)

- Lactic Dehydrogenase Immunological Test System (866.5560)
- Lactoferrin Immunological Test System (866.5570)
- Lipoprotein X Immunological Test System (866.5590)
- Plasminogen Immunological Test System (866.5715)
- Prothrombin Immunological Test system (866.5735)
- Retinol-Binding Protein Immunological Test System (866.5765)
- Inter-Alpha Trypsin Inhibitor Immunological Test System (866.5890)

Pathology Panel (864)

- Cultured Animal and Human Cells (864.2280)

Obstetrics and Gynecology Pannel (884

- Unscented Menstrual Pad (884.5435)

Class II Devices

All Eligible Devices **EXCEPT**

Immunology Panel (866)

- Rheumatoid Factor Immunological Test System (866.5775)

Obstetrics / Gynecology Panel (884)

- Scented or Scented Deodorized Menstrual Tampon (884.5460)
- Unscented Menstrual Tampon (884.5470)